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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,290	05/08/2001	Norbert F Schnell	P 279455	2741
28120	7590	12/29/2003	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/831,290

Applicant(s)

SCHNELL ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 6 is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 5,8-13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s), \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This Office Action is a reply to the "Amendment" of 6 October 2003 (hereinafter, 6 October Paper) filed in response to the Non-Final Office Action mailed 3 April 2003 (hereinafter, 3 April Office Action). Claim 7 was withdrawn from consideration and claims 1-6 were considered in the 3 April Office Action. Claims 4-6 were amended and claims 8-13 were added in the 6 October Paper. Claims 1-13 are pending and claims 1-6 and 8-13 are under consideration.

### ***Election/Restrictions***

In the remarks, Applicant again request reinstatement of claim 7 in accordance with linking claim practice as set forth in MPEP §809. This argument is not found persuasive at least because the present case is a 35 USC §371 filing and as such is restricted according to the rules of Unity of Invention. Therefore, U.S. linking claim practice does not apply. Furthermore, as pointed out in the previous Office Action, claim 1 is not a necessary process of making the product of claim 7 because the inhibitor is not actually made by the screening assay. That is, the product of claim 7 could be identified by methods other than that of claim 1. Therefore, even under U.S. linking claim practice, claim 7 would not be rejoined with the elected invention.

### ***Response to Amendments***

#### **Claim Objections**

Objection to claim 6 is withdrawn.

Claim Rejections - 35 USC § 112

Claims 1 and 2 stand rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the full scope of the claimed subject matter.

Claims 1-3 stand rejected and newly added claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter for reasons of record and herein below in the response to arguments.

Rejection of claims 5 and 6 under 35 U.S.C. 112, first paragraph, as lacking an enabling disclosure is withdrawn.

***Response to Arguments***

Claim Rejections - 35 USC § 112

Claims 1 and 2 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the full scope of an engineered cell whose ability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids, and a method of using said engineered cell to assay for an IPC synthase inhibitor.

In response to the rejection, Applicant argues that the claims recite the cells' functional characteristics coupled with a known or disclosed correlation between function and structure. In addition, the specification amply teaches that cells comprising an *lcbl* allele and overexpressing a *SLC1-1* gene, whose capability to synthesize sphingolipids depends on the addition of

exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids, can be used in the claimed screening assay. Applicant urges, the specification provides both working examples and sufficient description of these functional characteristics that are coupled with correlation between function and structure of the cells.

These arguments have been fully considered but are not found persuasive because, although the specification discloses a single structure having the functional properties of the claimed engineered cells, the engineered cells of the rejected claims are not limited to comprising that structure. Therefore, the claims broadly encompass any engineered cell and method of using any engineered cell having the phenotype set forth in the claims. As the disclosure does not describe an engineered cell whose ability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids other than a cell comprising an *lcb1* allele and overexpressing SLC1-1, the skilled artisan would not have recognized that Applicant was in possession of the full scope of the claimed subject matter at the time of filing. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description.

Claims 1-3 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an engineered *S. cerevisiae* comprising the *lcb1*/SLC1-1 genotype and further overexpressing SLC-1, and a method identifying a selective IPC synthase inhibitor using said engineered *S. cerevisiae*, does not reasonably provide enablement for any and all cells having the phenotype of exogenous phytosphingosine dependent sphingolipid synthesis and

ability to grow via compensatory phospholipids or methods of identifying IPC synthase inhibitors using any and all cells having that phenotype.

In response to the rejection of record, Applicant argues that the Examiner's contention that the claims relate to any engineered cells is not the case because the specification indicates such cells must be able to function as a host for a fungal IPC synthase. While this is true, it would seem that any cell capable of synthesizing a fungal IPC synthase would meet the vague limitation of being able to function as a host. Therefore, the cell of the claim still encompasses widely varied cell types. Applicant argues that the specification describes other cells besides *S. cerevisiae* that may be used in the practice of the invention. However, the claims are not limited to these cell types.

Finally, Applicant points out that the specification illustrates that a convenient host strain for use in the assay methods of the invention is an *lcb1*/SLC1-1 strain which can be adapted for sustained growth, for example, by enhancing expression of the compensatory mutant SLC1-1 allele. Applicant is reminded that the Examiner has acknowledged that the *lcb1*/SLC1-1 strain overexpressing the SLC1-1 allele is enabled. However, the specification is silent with regard to how to make strains other than the *lcb1*/SLC1-1 strain overexpressing SLC1-1 having the phenotypic characteristics set forth in the claims.

Thus, for reasons of record and herein above, the claims are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter.

*New Grounds Necessitated by Amendment*

Claim Objections

Claim 11 and 12 are objected to because of the following informalities: The claims recite “[t]he method of clam 10” while claim 10 is directed to an assay. Although the meaning of the claim is not indefinite, it is preferable that the language used be consistent throughout the claims. Appropriate correction is required.

*Allowable Subject Matter*

Claims 5, 8-10 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Please note: Art Unit 1636 will be moving to the new USPTO facilities on 14 January 2004. After that date, Examiner Sullivan can be reached at 571-272-0779 and Examiner Yucel can be reached at 571-272-0781.

DMS

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER